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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,768	08/18/2003	Alexander V. Kukhtin	21416-93965	5089

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EXAMINER	
FORMAN, BETTY J	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,768	KUKHTIN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5 and 7-37* is/are pending in the application.

4a) Of the above claim(s) *16-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 3-5 7-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 20 September 2007 has been entered.

Status of the Claims

2. This action is in response to papers filed 20 September 2007 in which claims 1, 5, 7 were amended and claim 6 was canceled. The amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 28 February 2007 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection are discussed.

Claims 1, 3-5, 7-15 are under prosecution.

Claim Rejections - 35 USC § 112

35 U.S.C. 112: First Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-5, 7-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 (from which all other pending claims depend) has been amended to define the macroporous substrate as "having pore sizes that are specific to a biomolecule". Applicant points to ¶ 36 of the specification for support of the newly defined substrate. The cited passage teaches the following:

> Change in the nature and concentration of initial monomers, porogen, reaction temperature, and initiator of a radical polymerization allows production of polymer structures with a wide variety of average pore size (1-1000 nm) and physico-chemical properties such as transparency, hydrophilicity, and density. This allows control of polymer size to enable custom fabrication of substrates for microarrays designed to analyze complex biological molecules, e.g. proteins having a molecular weight of 150 kDa are analyzed with the macroporous polymer substrate.

The cited passage clearly teaches custom fabrication of polymer size for molecular analysis based on the molecular weight of the molecule. However, neither the cited passage nor the remaining text of the specification teach "pore sizes that are specific for a biomolecule" as newly claimed. Hence, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN

REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. *APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE*" (emphasis added).

35 U.S.C. 112: Second Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is indefinite for the recitation "the methacrylates" because the recitation lacks proper antecedent basis in Claim 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1, 3-5, 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent No. 6,994,964, filed 31 August 2000) and Chromecek et al (Patent Specification 1,188,736, published 22 April 1970, London England).

Regarding Claim 1, Chang et al disclose a method for making a microarray with a macroporous polymer substrate (Column 13, lines 11-18 and Example 1-2), the method

including obtaining a monomers (e.g. HEMA, Columns 13-15) to form a polymerization mix in the presence of a porogenic solvent (i.e. aliphatic alcohol Column 15, lines 50-62 as defined in the instant specification, ¶ 20) coating a surface with the substrate (e.g. glass or silicon, Column 21, lines 25-56) and adding biomolecules to the coated surface to form an array (Examples 1-3) and wherein the pore size is controlled by the composition of the polymerization mixture (Column 12, lines 21-28).

Chang is silent regarding the mono and polyfunctional monomers forming the polymerization mixture wherein the size of the macropores is provided by the volumes of porogenic solvent. However, it was well known in the art at the time the claimed invention was made that pore size is controlled by the amount of aromatic alcohol in the polymerization mixture as taught by Chromecek (page 2, lines 85-94, page 3, lines 15-26, 58-64).

Chromecek teach a macroporous polymer supporting substrate comprising mixing mono and polyfunctional monomers and initiating polymerization in the presence of porogenic solvent (page 1-4). Chromecek further teach the polymeric support provides "permanent macroporous structures which are advantageous for detecting and separating polar compounds (page 1, line 35-48)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the monomers and solvent-controlled pores as taught by Chromecek to the porous substrate of Chang. One of ordinary skill in the art would have been motivated to do so for the expected benefits of "permanent macroporous structures which are advantageous for detecting and separating polar compounds as taught by Chromecek (page 1, line 35-48)

Regarding Claim 3, Chang et al disclose the method further comprising obtaining at least one immobilization chemical for linking biomolecules to the substrate (e.g. activating group) and adding the chemical to the substrate (Column 5, lines 3-16).

Regarding Claim 4, Chang et al disclose the method wherein the surface is glass or silica (Column 2, lines 4-6).

Regarding Claim 5, Chang et al disclose the method wherein biomolecules (e.g. DNA, proteins, peptides, lipids, polysaccharides, etc) are immobilized on the surface (Column 16, lines 24-35).

Regarding Claim 7, Chang et al disclose the method wherein the monofunctional methacrylate is e.g. an alkyl, methacrylates, (Column 2, lines 10-33 and Column 6, lines 42-67).

Regarding Claim 8, Chang et al disclose the method wherein the polyfunctional methacrylate is di-methacrylate i.e. branched (Column 2, lines 10-33 and Column 6, lines 42-67).

Regarding Claim 9, Chang et al disclose the method wherein the methacrylate is HEMA (Example 1, Column 21, lines 25-56Column 27, lines 5-15).

Regarding Claims 10-11, Chang et al disclose the method wherein the porogenic solvent is an alcohol (Column 15, lines 50-52) but do not teach the aromatic alcohol. However, Chromecek teaches the similar polymer wherein the preferred solvent is a cyclo-alcohol (page 1, lines 65-66).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the aliphatic alcohol solvent of Chang with the cyclo-alcohol solvent of Chromecek. One of ordinary skill in the art would have been motivated to do so based on the similar functionality and well known use taught by Chromecek (page 1, lines 63-66).

The courts have stated that selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327. 65 USPQ 297. and In re Leshin, 227 F.2d. 197, 125 USPQ 416 (MPEP § 2144.07).

Regarding Claim 12, Chang et al disclose the method wherein the porogenic solvent is an aliphatic alcohol (Column 15, lines 50-52).

Regarding Claim 13, Chang et al disclose the method wherein the porogenic solvent is an aromatic alkyl derivative (Column 15, lines 21-62).

Regarding Claim 14, Chang et al disclose the method wherein the immobilization chemical is derivatized to include succinimide (Column 5, lines 10-16).

Regarding Claim 15, Chang et al disclose the method wherein the immobilization chemical is N-hydroxysuccinimide ether (Column 5, lines 10-16).

Response to Arguments

9. Applicant asserts that the instantly claimed method differs from that of Chang because the instantly claimed method applies monomer solutions between two surfaces with spacers of >10 microns and the initiates photopolymerization between the two surfaces to produce thick, not thin polymer brushes. The assertion is noted. However, the claims are not limited to a "thick" block, the claims do not define the "macroporous polymer" by any size or dimension, the claims do not require solution application between two surfaces, or polymerization between two surfaces, or photopolymerization or block copolymerization. Therefore, Applicant's arguments are not commensurate in scope with the claims. The claims merely require obtaining and mixing monomers in the presence of a porogenic solvent and initiating polymerization for form a macroporous polymer. The combination of Chang and Chromecek teach the method as claimed and detailed above.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

10. Claims 1, 3-5, 7-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (U.S. Patent No. 4,352,884, issued 5 October 1982) in view of Hammen et al (U.S. Patent Application Publication No. 2002/0043499, published 18 April 2002) and Chromecek et al (Patent Specification 1,188,736, published 22 April 1970, London England).

Regarding Claim 1, Nakashima et al disclose a method for making a microarray with a macroporous polymer substrate (Abstract, Column 3, lines 9-12 and Example 1-2), the method including obtaining mono and polyfunctional monomers (e.g. HEMA and GMA, Example 1) to form a polymerization mix in the presence of a porogenic solvent (i.e. aliphatic alcohol, Example 1) coating a surface with the substrate (Column 2, lines 48-58) and adding biomolecules to the coated surface to form an array (Column 3, lines 12-55).
and wherein the pore size is controlled by the composition of the polymerization mixture (Column 12, lines 21-28).

Nakashima is silent regarding the size of the macropores being provided or controlled by the volumes of porogenic solvent. However, it was well known in the art at the time the claimed invention was made that pore size is controlled by the amount of aromatic alcohol in the polymerization mixture as taught by Chromecek (page 2, lines 85-94, page 3, lines 15-26, 58-64).

Chromecek teach a macroporous polymer supporting substrate comprising mixing mono and polyfunctional monomers and initiating polymerization in the presence of porogenic solvent (page 1-4). Chromecek further teach the polymeric support provides "permanent macroporous structures which are advantageous for detecting and separating polar compounds (page 1, line 35-48)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the monomers and solvent-controlled pores as taught by Chromecek to the porous substrate of Nakashima. One of ordinary skill in the art would have been motivated to do so for the expected benefits of "permanent macroporous structures which

are advantageous for detecting and separating polar compounds as taught by Chromecek (page 1, line 35-48).

Nakashima et al further teach the macroporous support is for the immobilization of bioactive materials and specifically teaches biomolecule immobilization (Abstract, Column 3) but they are silent regarding immobilizing to form a microarray. However, macropolymer supports for immobilizing biomolecules to form a microarray were well known at the time the claimed invention was made as taught by Hammen.

Hammen teaches a similar method of polymerization of monomers to from a macroporous polymer support (Examples) having immobilized biomolecules wherein the preferred support is in the form or any array thereby providing for massively parallel analysis (¶ 74). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the immobilization of Nakashima by immobilizing the biomolecules in an array format. One of ordinary skill in the art would have been motivated to do so for the expected benefit of thereby providing for massively parallel analysis of the biomolecules as desired in the art as taught by Hammon (¶ 74).

Regarding Claim 3, Nakashima et al disclose the method further comprising obtaining at least one immobilization chemical for linking biomolecules to the substrate and adding the chemical to the substrate (Column 3, lines 54-68).

Regarding Claim 4, Nakashima et al disclose the method wherein the surface is glass or silica, plastic, vinyl (Column 2, lines 547-58).

Regarding Claim 5, Nakashima et al disclose the method wherein biomolecules (e.g. DNA, proteins, peptides, lipids, polysaccharides, etc) are immobilized on the surface (Column 3, lines 13-32).

Regarding Claim 7, Nakashima et al disclose the method wherein the monofunctional monomer is HEMA (Example 1, Column 6, lines 63-68).

Regarding Claim 8, Nakashima et al disclose the method wherein the polyfunctional monomer is di-methacrylate gylcidyl methacrylate (Example 1, Column 6, lines 63-68).

Regarding Claim 9, Nakashima et al disclose the method wherein the methacrylate is HEMA and glycidyl methacrylate (Example 1, Column 6, lines 63-68).

Regarding Claims 10-11, Nakashima et al disclose the method wherein the porogenic solvent is an aliphatic alcohol (Column 6, lines 63-68) but do not teach the aromatic alcohol. However, Chromecek teaches the similar polymer wherein the preferred solvent is a cyclo-alcohol (page 1, lines 65-66).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the aliphatic alcohol solvent of Chang with the cyclo-alcohol solvent of Chromecek. One of ordinary skill in the art would have been motivated to do so based on the similar functionality and well known use taught by Chromecek (page 1, lines 63-66).

The courts have stated that selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327. 65 USPQ 297. and In re Leshin, 227 F.2d. 197, 125 USPQ 416 (MPEP § 2144.07).

Regarding Claim 12, Nakashima et al disclose the method wherein the porogenic solvent is an aliphatic alcohol (Column 6, lines 63-68).

Regarding Claims 14-15, Nakashima et al disclose the method wherein the immobilization chemical is N-hydroxysuccinimide ether (Column 3, lines 65-68).

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Primary Examiner
Art Unit: 1634
December 27, 2007